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09/702,037	10/27/2000	Peter Bennett Duff Whyte	U013032-6	8344

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EXAMINER

WARE, DEBORAH K

ART UNIT

1651

PAPER NUMBER

28

DATE MAILED: 01/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/702,037

Applicant(s)

WHYTE, PETER BENNETT DUFF

Examiner

Deborah K. Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 3-4 and 11-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4 and 11-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☒ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

Claims 1, 3-4 and 11-27 are presented for reconsideration on the merits.

Applicant's amendment after final will be entered and the finality of last Office action is hereby withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-4 and 11-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite for the recitation of "the retentate" at line 4, since it is unclear that the retentate is recovered as said fraction. Thus, it is suggested to insert –as said fraction—after "the retentate" at line 4. Also it is suggested to insert –retentate—before "fraction" at line 4. Therefore, with these changes it is further suggested to delete "maintained within the retentate following ultra-filtration of the colostrum" at lines 5-6. Claims 3-4 and 11-27 are rendered vague and indefinite for those reasons set forth above for claim 1.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over **newly applied** AU-A-63136/94 (Peter Bennett Duff Whyte) (AG-page 1 of 1 filed December 1, 2000) in view of **newly applied** WO 97/16977 (AG-page 1 of 3 filed August 5, 2002), both cited on a previously submitted PTO-1449 Form.

Claims 1 and 3-4 are drawn to a colostrum food product prepared by a method comprising subjecting colostrum to ultra-filtration to obtain an ultra-filtered colostrum retentate, and recovering the retentate, wherein said fraction includes colostrum-derived growth factors and casein maintained within the retentate following ultra-filtration of the colostrum.

AU-A-63136/94 teaches a colostrum product prepared by a method comprising subjecting colostrum to ultra-filtration to obtain an ultra-filtered colostrum retentate, and recovering the retentate, wherein said product is further subjected to a spray drying process. Note page 1 and claim 1 of the this cited patent. The ultra-filtration process removes preferably, all molecules of molecular weight less than 20,000 for example, water, minerals, salts, and non-protein nitrogen. Note further page 3, lines 28-35. Also the immuno-proteins are heat sensitive and disclosed to be contained in the colostrum, note bridging pages 3-4, lines 35-40 and lines 1-5, respectively (note : i.e. growth factors such as IGF-I). Also note page 6, lines 10-15, wherein the reference discloses that the retentate is recovered for spray drying. Further, note at page 7, lines 8-15, that after the spray drying the colostrum product is packed in new food grade bags.

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WO 97/16977 teaches colostrum for use in food products (i.e. dairy products), note the abstract. Further, the reference discloses that colostrum can be prepared so as to reduce the bioburden of colostrum while retaining the biological activity of certain proteins including the immunoglobulin fraction, see abstract. The dairy products or food products containing the colostrum include milk, cream, yoghurt, sport drinks, custards, cheese, cottage cheese and ice creams.

The claims differ from AU-A-63136/94 in that a food product containing colostrum is not disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was filed to use a recovered colostrum retentate disclosed by AU-A-63136/94 in a food product as disclosed by WO 97/16977. The presence of casein and growth factors are intrinsic to the retentate of AU-A-63136/94 because only salts and minerals are removed as taught by this reference, and further because growth factors such as immunoproteins, are taught, or at least suggested, by this reference to be a desired component to retain in the colostrum and such components are also taught to be retained by the colostrum for use in a food product as disclosed by WO 97/16977, see abstract. Thus, since casein fractionates with the growth factors it is, therefore, intrinsic to the retentate disclosed by AU-A-63136/94. Therefore, it would have been obvious to one of skill in the art to combine the above cited teachings in order to provide for a food composition comprising colostrum prepared by ultra-filtration process, casein, and colostrum derived growth factors (i.e. IGF-1).

The latter of which is an immunoglobulin protein or immunoprotein. Clearly one of skill in the art would have expected successful results for obtaining such a product and such ingredients of the product being well known in the art to be derived from colostrum of which is the milk secreted by a mammal just before and for a short period after giving birth and thus, fed to the offspring. Colostrum in this form is hence in the form of a food product in nature and would have been expected to provide successful results in a man-made food product. The claims are, therefore, *prima facie* obvious over the newly cited prior art.

Claims 11-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over AU-A-63136/94 and WO 97/16977 as applied to claims 1 and 3-4 above, and further in view of Clark et al(AS-sheet 1 of 3 filed August 5, 2002) and AU-A-39340/89 (AF-sheet 1 of 3 filed August 5, 2002), both cited on a previously submitted PTO-1449 Form.

Claims 11-27 are drawn to methods of changing body composition and/or physical work capacity, increasing tissue mass, physiological buffering capacity, height, recovery after exercise and fat utilization, endurance exercise performance, reducing fat mass, physiological fatigue and/or an individual's perception of their own fatigue, muscle damage during exercise, treating or preventing a disorder of the gut, improving gut growth and development, improving vertical jump performance, ability to generate peak power and peak force, and bioavailability of components in colostrum which lead to changed work capacity and/or body composition, and further for treating short bowel syndrome. Wherein in each of the above claimed methods a step of administering the

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food composition of claims 1 and 3-4 is carried out in order to achieve each of the resultant claimed methods.

Clark et al teach that immunoglobulins found in colostrum are able to neutralize the most harmful bacteria, viruses and yeasts, note page 1, lines 20-30. Also the presence of growth factors such as IGF-1 enable the body to burn fat which are essential for processing fat for energy and hence building muscle, note page 43, see lines 25-40 of second column. Further, improved body composition and condition is achieved by the presence of IGF-1 levels, note page 44, lines 1-20. Also reduction of muscle damage during exercise by enhancing healing is disclosed, see page 44-45, all lines and page 46, lines 22-35. Further, it is also disclosed that colostrum is a food and promotes healing of the body composition by ridding the body of toxins and reducing fatigue, note page 51, lines 30-50. Also improved exercise performance is noted, see page 55, lines 8-30.

AU-A-39340/89 teaches a method of treating or preventing a disorder of the gut, see page 1, all lines and lines 35-40, improving gut growth and development, see page 1, lines 10-25, treating bowel syndrome, see page 1, lines 15-25. Also note page 2, lines 1-10 and lines 20-35 and further, pages 2-3, all lines, page 4, lines 12-25.

The claims differ from the teachings of AU-A-63136/94 and WO 97/16977 in that the resultant methods are not clearly disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was filed to carry out a step of administering the food composition as disclosed by AU-A-63136/94 and WO 97/16977 in each of the methods disclosed by

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Clark et al and AU-A-39340/89 to obtain the above resultant methods of changing body composition and/or physical work capacity, increasing tissue mass, physiological buffering capacity, height, recovery after exercise and fat utilization, endurance exercise performance, reducing fat mass, physiological fatigue and/or an individual's perception of their own fatigue, muscle damage during exercise, treating or preventing a disorder of the gut, improving gut growth and development, improving vertical jump performance, ability to generate peak power and peak force, and bioavailability of components in colostrum which lead to changed work capacity and/or body composition, and further for treating short bowel syndrome. Each of the cited references disclose methods, or at least suggest these methods, of administering colostrum for obtaining the desired resulting effects. The results of the methods are intrinsic to the composition disclosed by AU-A-63136/94 and WO 97/16977. The methods of administering colostrum of which is also disclosed by Clark et al to be a food product are taught, or at least suggested, by the above noted secondary cited prior art. One of skill in the art would have expected successful results for administering a food product containing colostrum, growth factors and casein and the step of administering such a food composition is clearly recognized by the cited prior art. The claims are prima facie obvious over the cited prior art.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on a previously submitted PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.


No claims are allowed.

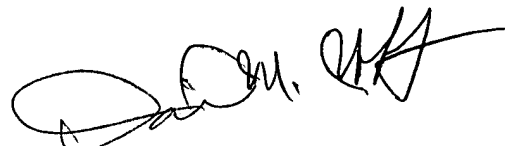
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 308-4245. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 308-4743. The fax phone number for the organization where this application or proceeding is assigned is 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-0196.

  
Deborah K. Ware  
December 27, 2003

  
DAVID M. NAFF  
PRIMARY EXAMINER  
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